

## **Iowa General Assembly**

## **2014 Committee Briefings**

Legislative Services Agency – Legal Services Division

https://www.legis.iowa.gov/committees/committee?ga=85&session=2&groupID=21380

## CANNABIDIOL IMPLEMENTATION STUDY COMMITTEE

Meeting Dates: September 11, 2014

**Purpose.** This compilation of briefings on legislative interim committee meetings and other meetings and topics of interest to the lowa General Assembly, written by the Legal Services Division staff of the nonpartisan Legislative Services Agency, describes committee activities or topics. The briefings were originally distributed in the lowa Legislative Interim Calendar and Briefing. Official minutes, reports, and other detailed information concerning the committee or topic addressed by a briefing can be obtained from the committee's Internet page listed above, from the lowa General Assembly's Internet page at <a href="https://www.legis.iowa.gov/">https://www.legis.iowa.gov/</a>, or from the agency connected with the meeting or topic described.

## **CANNABIDIOL IMPLEMENTATION STUDY COMMITTEE**

September 11, 2014

**Co-chairperson:** Senator Joe Bolkcom **Co-chairperson:** Representative Walt Rogers

**Background.** The Cannabidiol Implementation Study Committee was created by the Legislative Council for the 2014 Interim and approved to hold one meeting. The charge of the committee is to monitor the implementation of the limited legalization of use in this state of cannabidiol, to consider whether the new law is helping the people it is supposed to help, and to review the University of lowa College of Medicine research study called for by the legislation.

**Medical Cannabidiol Act Overview.** Ms. Rachele Hjelmaas, Senior Legal Counsel, LSA Legal Services, provided a summary overview of 2014 lowa Acts, SF 2360, the Medical Cannabidiol Act. The Act includes the following:

- Allows for the medical use of cannabidiol, as defined in the Act, for alleviating symptoms caused by intractable
  epilepsy under certain narrowly defined conditions. An lowa neurologist who has examined and treated a patient
  suffering from intractable epilepsy may provide but has no duty to provide a written recommendation for the
  patient's medical use of cannabidiol to treat or alleviate symptoms of intractable epilepsy, if certain criteria are
  met
- A recommendation for the possession or use of cannabidiol shall be provided exclusively by a patient's in-state neurologist, shall be obtained from an out-of-state source, and shall only be recommended for oral or transdermal administration.
- The lowa Department of Public Health (DPH) may approve the issuance of annual and renewal cannabidiol registration cards by the lowa Department of Transportation (DOT) to a patient and to a primary caretaker of the patient who is at least 18 if certain criteria are met, and the patient or primary caretaker submits an application to DPH with certain information.
- A patient must be a permanent resident of lowa.
- DPH is required to maintain a confidential file of the names of each patient and primary caregiver issued a cannabidiol registration card. However, certain information may be released to authorized persons under certain circumstances.
- The Act provides affirmative and complete defense provisions from criminal prosecution in this state for qualifying neurologists, patients, and primary caregivers who comply with the provisions of the Act for activities arising directly out of or directly related to the recommendation or use of cannabidiol in the treatment of a patient diagnosed with intractable epilepsy, and these defenses apply only if the quantity of cannabidiol oil does not exceed 32 ounces per patient.
- A person who knowingly or intentionally possesses or uses cannabidiol in violation of the Act is subject to the

penalties of Iowa Code chapters 124 (Controlled Substances Act) and 453B (Excise Tax on Unlawful Dealing in Certain Substances).

- The Act is repealed July 1, 2017.
- The University of Iowa Carver College of Medicine and College of Pharmacy are required to submit an annual report detailing the scientific literature, studies, and clinical trials regarding the use of cannabidiol on patients diagnosed with intractable epilepsy to the DPH and the General Assembly on or before July 1 of each year beginning July 1, 2015.

**Rulemaking Process and Implementation—Update.** Ms. Deborah Thompson, Policy Advisor and Healthiest State Initiative Coordinator, DPH, and Ms. Kim Snook, Director of Driver Services, and Mr. Mark Lowe, Motor Vehicle Division Director, DOT. Ms. Thompson presented an overview of the DPH administrative rulemaking process intended to implement the registration card program, including the application process, and Ms. Snook and Mr. Lowe answered specific committee member questions about the DOT issuance of the registration cards, including expected costs to DOT associated with the issuance.

Ms. Thompson stated that the administrative rules were written in collaboration to reflect the language in SF 2360 with DOT and key stakeholders. Notice of Intended Action was published in the August 6, 2014, Iowa Administrative Bulletin. The majority of public comments to the noticed rules recommended changes to the legislation and therefore fell outside of the scope of the administrative rules. The State Board of Health adopted some changes to the noticed rules on September 10, 2014, including a revised definition of "permanent resident," an additional option for valid photo identification in the application process, and revisions to the renewal process. The department also removed the requirement for the recommending neurologist to physically examine a patient before issuing a written recommendation to better align with SF 2360 and added additional language to clarify that aggregate and statistical information that does not provide any patient identifiers can be made available to the public upon request. The rules become effective January 30, 2015.

Ms. Thompson also provided a flowchart on the basic card application process. Ms. Snook and Mr. Lowe answered questions about DOT's role in issuing the cannabidiol registration cards, as well as funding concerns.

Committee members expressed concern about getting people the help they so desperately need under the law and raised concerns about the January 30, 2015, implementation date. Some members suggested that other administrative processes might have sped up the implementation of the law. Ms. Thompson responded that both the DPH and DOT have made every effort to work as quickly as possible to implement the law, and that there are many moving parts to work through and that additional details are still being worked out. She also noted that DPH may be able to allow people to apply earlier and have the registration cards ready prior to the January 30 date.

Cannabidiol Research Studies. Dr. Charuta Joshi, Clinical Associate Professor of Pediatrics with specialties in Neurology and Epilepsy, University of Iowa Carver College of Medicine, provided information on scientific research evaluating the role of cannabidiol in the control of refractory seizures. She explained that two strains of cannabis exist: Sativa, which contains more THC (tetrahydrocannabinol) and indica which contains more CBD (cannabidiol). THC is the psychoactive component of cannabis that produces a high, and CBD is a nonpsychoactive component. Depending upon variables involved in the process of production and processing of cannabis, such as temperature, fertilizer, etc., the concentration of THC and CBD can vary greatly and cannabis on the street may be pure THC. Dr. Joshi stated that intractable epilepsy is based on a person not responding to two or more effective medications, not on the number of seizures a person experiences. She further explained that in a number of research studies, CBD has been shown to be effective as an anticonvulsant in some patients, although what dosage is effective is not known, and that in such research, the use of CBD had no life-threatening side effects. In contrast, the 15-20 medications currently used as anticonvulsants for persons with epilepsy and other psychiatric illnesses have resulted in negative side effects including liver and kidney toxicity. CBD also has been found to not have addictive potential as some other medications do.

Dr. Joshi also noted that when plant extracts are used, there is no way to ensure the ratio of CBD to THC without standardization; however GW Pharmaceuticals is developing a standardized pure strain of CBD. The University of Iowa will be taking part in double-blind studies sponsored by GW Pharmaceuticals to learn more about cannabidiol in ways doctors have not been able to do so far. Participating patients may or may not be from Iowa. The product that will be used at the University of Iowa Children's Hospital test site in the double-blind studies is from a cloned plant that produces pure CBD and is a consistent product. GW Pharmaceuticals will provide all of the CBD used in the study. GW Pharmaceuticals has provided CBD to hundreds of children in the United States with no resultant life-threatening side effects. The results of the study will be in the public domain.

Committee members posed questions to Dr. Joshi about the research studies including questions relating to the purity of the cannabidiol that patients might obtain now from other states. Dr. Joshi stated that the concern is not with CBD per se but as for standardization of the product and the effective concentration amount. She noted that the lowa Board of Pharmacy had also requested a literature review regarding medical cannabis.

Personal and Professional Perspectives—Impact Panel. Ms. Sally Gaer, Ms. Maria LaFrance, and Ms. April Stumpf, medical cannabidiol consumer advocates; Ms. Roxanne Cogil, Iowa Epilepsy Foundation; and Dr. David Moore, a

neurologist specializing in epilepsy and a member of the Iowa Neurological Association, offered personal and professional perspectives on the impact of SF 2360. Ms. Gaer, Ms. LaFrance, and Ms. Stumpf are all parents of children with intractable epilepsy and were very involved in the efforts supporting SF 2360 during the 2014 Session. They thanked legislators for their work and support in passing the legislation, but expressed concerns with the restrictions in the law that prevent families from getting in-state access to the medical cannabidiol they are in desperate need of to treat their children.

- Ms. Gaer, the parent of an adult daughter with Dravet Syndrome, a chronic illness characterized by persistent seizures, provided comments advocating for in-state access for medical cannabidiol in lowa and the need for instate medical dispensaries and greenhouse growing regulations. She also proposed lowa legislators take a field trip to other states with medical cannabis dispensaries to research well-run cannabis dispensary programs.
- Ms. LaFrance spoke about her six-year-old son, who also suffers from Dravet Syndrome, and the dangerous side
  effects of his prescription medication. She also spoke about access concerns as well as the excessive costs
  families face and suggested lowa should look to states like Oregon, New Mexico, and Colorado for examples of a
  well-run cannabis program.
- Ms. Stumpf, a parent of a two-year-old daughter who has 50-70 seizures per day, commented that prescription
  medication has not been effective in managing her daughter's illness. She urged committee members to remove
  the legal and financial barriers from the current legislation and to allow the lowa Department of Agriculture or
  other entity to supervise and control the production of in-state greenhouse dispensaries.
- Ms. Cogil, also a parent of a child with intractable epilepsy, echoed the parents' concerns that the law does not provide meaningful access to cannabidiol because the law does not allow for the in-state production, processing, and dispensing of cannabidiol, which means that persons in lowa in need of cannabidiol have to travel out of state to obtain the cannabidiol, risking violations of other state and federal laws.
- Dr. Moore, who treats patients with epilepsy and who himself suffers from epilepsy, expressed concern about the
  fact that although approximately 3 percent of lowa's population have epilepsy (more than 90,000), only about
  12,000 patients are potential candidates for medical cannabidiol under the restrictions in the law. He also
  expressed concern about the financial burden on families in accessing and using the cannabidiol oil, and that few
  neurologists practicing in lowa even treat patients with epilepsy.

**Public Comment.** Individual commenters included comments from parents of children with intractable epilepsy and persons suffering from other chronic illnesses including chronic pain syndrome, cancer, Ehlers–Danlos Syndrome (EDS) (an inherited connective tissue disorder), and other debilitating illnesses, who spoke about the medical benefits of cannabidiol oil and other forms of medical cannabis as well as financial and legal obstacles to out-of-state access.

**Committee Discussion and Recommendations.** Each member of the committee was invited to make recommendations and committee members discussed and voted on each recommendation. The recommendations approved by the committee for further consideration by the General Assembly are summarized as follows:

- Develop a regulated program to produce, process, and dispense medical cannabis and further recommend that
  medical cannabis not be taxed by the state at any stage of producing, processing, or dispensing the medical
  cannabis.
- Reschedule marijuana from a schedule I controlled substance to a schedule II controlled substance.
- Further investigate access, standardization, and legalization of cannabidiol.

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